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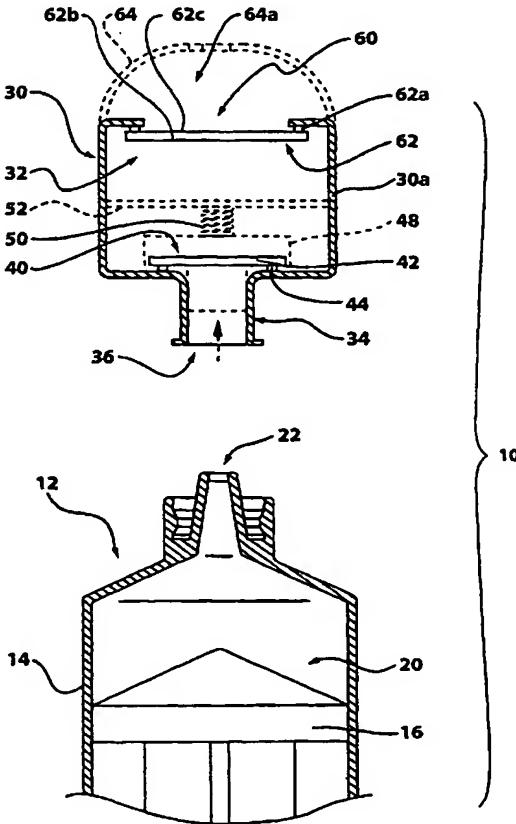
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[Continued on next page]

(54) Title: DEVICE AND METHOD FOR CONTROLLED EXPRESSION OF GASES FROM MEDICAL FLUIDS DELIVERY SYSTEMS



(57) Abstract: Disclosed herein is a syringe assembly for discharging gaseous materials from a syringe, comprising an elongate container (14) with a plunger (16) slidably and sealingly engaged therein to form a fluid material receiving cavity (20), the container further comprising an outlet (22) for dispensing fluid materials from the cavity; the plunger including transfer means for transferring gas constituents from the cavity to a region outside the cavity, or a gaseous material collection housing (36) being provided for emitting gaseous materials and retaining non-gaseous materials.



(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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— with amended claims

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

AMENDED CLAIMS
received by the International Bureau on 10 August 2004 (10.08.2004)
original claims 1 to 36 replaced by claims 1 to 34

CLAIMS:

1. A syringe assembly, comprising:

- an elongate container with a plunger slidably and sealingly engaged therein to form a cavity to receive fluid materials, the fluid materials including a nongaseous constituent and a gaseous constituent, the container further comprising a first outlet for dispensing fluid materials from the cavity under the action of the plunger;
- a gaseous material collection housing having a fluid materials receiving chamber, the housing having a first inlet to couple with the first outlet;
- a first inlet valve portion for controlling the passage of the fluid materials through the first inlet; and
- the housing having a second outlet and a second outlet valve portion for controlling the passage of the gaseous constituent from the chamber through the second outlet to a region outside the housing while retaining the non-gaseous constituent within the chamber.

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2. An assembly as defined in claim 1, wherein the first valve portion includes a valve plate sealingly anchored with the housing adjacent the first inlet, a slitted disk, a check valve, a duck bill valve, a ball valve, or a combination of two or more thereof.

3. An assembly as defined in claim 1 wherein the second outlet valve portion includes a 20 hydrophobic media layer.

4. An assembly as defined in claim 3 wherein the hydrophobic media layer includes a first surface facing the chamber and an opposite second surface, the second outlet valve portion further including an external housing adjacent the second surface.

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5. An assembly as defined in claim 2 wherein the valve plate is spring biased to a closed position to form a unidirectional valve.
6. An assembly as defined in claim 1 wherein the second outlet valve portion includes a hydrophobic filter media layer sealingly anchored with the housing adjacent the second outlet.
- 5 7. An assembly as defined in claim 6 wherein the hydrophobic filter media layer includes a substantially wetting membrane or a substantially nonwetting membrane.
8. An assembly as defined in claim 1 wherein at least a portion of the housing is arranged to view fluid materials accumulating therein.
9. An assembly as defined in claim 8 wherein the portion is transparent or translucent.
- 10 10. An assembly as defined in claim 9 wherein substantially the entire housing is transparent or translucent.
11. A syringe assembly for discharging gaseous materials from a syringe, comprising an elongate container with a plunger slidably and sealingly engaged therein to form a fluid material receiving cavity, the container further comprising an outlet for dispensing fluid materials from the cavity; the plunger including transfer means for transferring gas constituents from the cavity to a region outside the cavity, the plunger further including at least one passage and a hydrophobic filter layer extending across the passage.
- 15 12. A method for discharging gaseous materials from a medical materials dispenser, comprising the steps of:
 - 20 - filling a medical materials dispenser with fluid materials;

- fitting an outlet of the dispenser with an inlet of a collection housing which is arranged to receive fluid materials from the syringe cavity and which has the capability of selectively emitting a gaseous constituent, of the material from the housing, and of retaining one or more non-gaseous fluid constituents in the housing;

5 - orienting the dispenser to collect the gaseous constituent adjacent the outlet; and

- activating the dispenser so that at least the gaseous constituent exits the outlet and enters the housing wherein the dispensing step may include the emission of the gaseous constituent from the housing while the non-gaseous residual materials are substantially retained therein.

10 13. A method as defined in claim 12 further comprising the steps of removing the collection housing from the dispenser and actuating the dispenser to administer the fluid materials.

14. A method as defined in claim 13 wherein the dispenser includes a includes a syringe, an IV device, a catheter, or a combination of one or more thereof.

15 15. A process for treating a mammalian patient, which comprises:

- extracting an aliquot of the patient's blood with a first medical materials dispenser;
- subjecting the aliquot of blood extracorporeally to at least one stressor selected from an oxidative environment, UV radiation and elevated temperature up to about 45° C.;
- delivering the so-treated aliquot of blood to a chamber of a second medical materials dispenser;

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- fitting an outlet of the second medical materials dispenser with an inlet of a residual material collection housing which is arranged to receive residual fluid materials from the chamber and which has the capability of emitting a gaseous component of the material from the housing, and of retaining substantially all non-gaseous fluid materials in the housing;
- orienting the second medical materials dispenser to collect, at the outlet, a gaseous constituent in the fluid material within the chamber;
- dispensing the medical materials dispenser so that at least the gas constituent exits the outlet and enters the housing, and thereafter;

10 - administering the so-treated aliquot of blood from the second medical materials dispenser to the patient.

16. A process as defined in claim 15, wherein the oxidative environment stressor to which the blood aliquot is subjected is a mixture of medical grade oxygen and ozone, with an ozone content from about 0.1-100 μ g/ml, the ultraviolet radiation stressor is ultraviolet radiation from UV lamps emitting primarily at wavelengths of 280 nm or shorter, and the elevated temperature stressor is a temperature in the range from about 38-43° C.

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17. A process as defined in claim 15 wherein the blood aliquot is of volume of about 0.1 ml to 400 ml.

18. A process according to claim 16 wherein the chosen stressor or combination of stressors is applied to the blood aliquot for a period of time from 0.5-60 minutes.

19. A process as defined in claim 15, wherein the oxidative environment stressor to which the blood aliquot is subjected is a mixture of medical grade oxygen and ozone, with an ozone content from about 0.1-100 $\mu\text{g}/\text{ml}$.
20. A process as defined in claim 15 wherein the ultraviolet radiation stressor is ultraviolet radiation from UV lamps emitting primarily at wavelengths of 280 nm or shorter.
21. A process as defined in claim 15 wherein the elevated temperature stressor is a temperature in the range from about 38-43° C.
- 10 22. A delivery device, comprising an elongate container with a plunger slidably and sealingly engaged therein to form a fluid material receiving cavity, the container further comprising a first outlet and a gas discharge means for discharging gases from the cavity under the action of the plunger and dispensing means for dispensing fluid materials from the cavity under the action of the plunger, wherein the gas discharge means includes a transfer portion formed on the plunger for transferring a gas constituent from the cavity to a region outside the cavity.
- 15 23. A gas collection device for a medical fluid delivery system, comprising:
 - a gaseous material collection housing having an inner gaseous material receiving chamber, the housing having a housing inlet to couple with an outlet of the medical fluid delivery system;
 - an inlet valve portion for controlling the passage of the gaseous material through the housing inlet; and
 - 20 - the housing having a housing outlet and a housing outlet valve portion for controlling the passage of gaseous material from the chamber through the outlet to a region outside the housing while retaining non-gaseous materials within the chamber.
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24. A device as defined in claim 23, wherein the inlet valve portion includes a valve plate sealingly anchored with the housing adjacent the inlet.

25. A device as defined in claim 24 wherein the valve plate is spring biased to a closed position to form a unidirectional valve.

5 26. A device as defined in claim 23 wherein the housing outlet valve portion includes a hydrophobic filter media layer sealingly anchored with the housing adjacent the second outlet.

10 27. A device as defined in claim 23 wherein the medical fluids delivery system includes a syringe, an IV device, a catheter, or a combination of one or more thereof.

28. A device as defined in claim 23 wherein the housing takes the form of a cap and is operable to seal the outlet of the medical fluids delivery system when not in use.

15 29. An assembly for discharging gaseous materials from a medical fluid supply device comprising medical fluid dispensing means, the fluid material dispensing means having first outlet means, collection means having a gaseous material receiving means with first inlet means to couple with said first outlet means, second outlet means for emitting gaseous materials from said gaseous material receiving means, second outlet valve means for controlling the emission of gaseous material from said receiving means through said outlet means to a region exterior thereto while retaining non-gaseous materials within the receiving means.

20 30. An assembly as defined in claim 29 further comprising first inlet valve means for controlling the passage of the gaseous material through said first inlet means.

31. An assembly as defined in claim 30 wherein the second outlet valve means includes hydrophobic filter means.

32. An assembly as defined in claim 29 wherein the medical fluid dispensing means includes a syringe, an IV device, or a catheter, or a combination thereof.

33. A process for treating a mammalian patient, which comprises:

- a step for extracting an aliquot of the patient's blood with a first medical materials dispenser;
- a step for subjecting the aliquot of blood extracorporeally to at least one stressor selected from an oxidative environment, UV radiation and elevated temperature up to about 45° C.;
- a step for delivering the so-treated aliquot of blood to a chamber of a second medical materials dispenser;
- a step for fitting an outlet of the second medical materials dispenser with an inlet of a residual material collection housing which is arranged to receive fluid materials from the chamber and which has the capability of emitting a gaseous component of the material from the housing, and of retaining substantially all non-gaseous fluid materials in the housing,
- a step for orienting the second medical materials dispenser to collect, at the outlet, a gaseous constituent in the fluid material within the chamber;
- a step for dispensing the medical materials dispenser so that at least the gas constituent exits the outlet and enters the housing, and thereafter;
- a step for administering the so-treated aliquot of blood from the second medical materials dispenser to the patient.

34. A dispenser assembly, comprising:

- an elongate container with a plunger slidably and sealingly engaged therein to form a cavity to receive fluid materials, the fluid materials including a nongaseous constituent and a gaseous constituent, the container further comprising a first outlet for dispensing fluid materials from the cavity under the action of the plunger;
- a gaseous material collection housing having a fluid materials receiving chamber, the housing having a first inlet to couple with the first outlet; and
- the housing having a second outlet and a valve assembly for controlling the passage of the gaseous constituent from the chamber through the second outlet to a region outside the housing while retaining the non-gaseous constituent within the chamber; the valve assembly including a first valve portion including an hydrophobic media layer and a normally closed second valve portion spaced from the first valve portion to form an intermediate chamber therebetween.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CA 03/01645

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/31 A61M5/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|--|-----------------------|
| X | US 3 978 846 A (BAILEY DONALD L) 7 September 1976 (1976-09-07) abstract column 3, lines 21-62; figures 2,3 ----- | 1-11, 36 |
| X | US 4 137 917 A (COHEN MILTON J) 6 February 1979 (1979-02-06) abstract; figures 7,8 ----- | 1,2,4,5, 7,8,36 |
| X | EP 0 462 702 A (SMITHS IND MED SYST INC) 27 December 1991 (1991-12-27) the whole document ----- | 1 |
| A | GB 1 297 794 A (-) 29 November 1972 (1972-11-29) the whole document ----- ----- | 2,3,6, 24-34 |
| | | -/- |

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the International filing date
- *L* document which may throw doubts on priority, claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the International filing date but later than the priority date claimed

- *T* later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the International search

27 May 2004

Date of mailing of the International search report

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Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/CA 03/01645

| C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT | | |
|--|---|-----------------------|
| Category | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| A | US 5 062 828 A (WALTZ ROGER L) 5 November 1991 (1991-11-05) the whole document ----- | 9-11 |
| P, X | US 2002/165496 A1 (THOMPSON GAREY) 7 November 2002 (2002-11-07) the whole document ----- | 1 |
| X | US 5 045 096 A (QUANG MINH B ET AL) 3 September 1991 (1991-09-03) the whole document ----- | 24-34 |
| X | US 3 631 654 A (RIELY PHYLLIS ET AL) 4 January 1972 (1972-01-04) abstract; figures 3-5 ----- | 24, 25, 28-34 |

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA 03/01645

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 13-22, 35
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy. In claims 13-15, the discharging process is normally carried out just before an injection.
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
1-11, 24-34, 36
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Claims Nos.: 13-22,35

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy. In claims 13-15, the discharging process is normally carried out just before an injection.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-11,36

A syringe/dispenser assembly with an elongate container and a plunger, a gaseous material collection housing with two outlets, at least one of which provided with a valve

2. claims: 12,23

A syringe assembly/delivery device with an elongate container and a plunger with gas transfer means.

3. claims: 24-34

Gas collection device/gas discharging assembly with two outlets provided with different kinds of valves and/or connectable with different medical fluids delivery systems.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/CA 03/01645

| Patent document cited in search report | | Publication date | | Patent family member(s) | | Publication date |
|--|----|------------------|--|---|--|--|
| US 3978846 | A | 07-09-1976 | NONE | | | |
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| US 3631654 | A | 04-01-1972 | BE DE GB IL | 739793 A 1949038 A1 1242487 A 33031 A | | 16-03-1970 09-04-1970 11-08-1971 28-09-1972 |